Additional Comment from the United States on the Code Chapter on Bovine Spongiform Encephalopathy
December 2003 Report of the Terrestrial Animal Health Standards Commission

Comments Submitted April 9, 2004

The United States would like to submit to the OIE for consideration by the Terrestrial Animal Health Code Commission the following additional comments related to the Code Chapter on BSE.

Article 2.3.13.1:

The United States requests that Article 2.3.13.1 be modified to exclude gelatins for which there is no significant exposure to humans or animals. Specifically, Article 2.3.13.1, Subpart 1) we recommend adding the following wording to Subpart 1:

e) gelatin from bone used solely for industrial use gelatins including use in photographic products, medical devices with no significant human or animal contact, and in vitro medical devices.

Rationale: The recommendations made in the OIE report are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle. In Article 2.3.13.1, Subparts 1 and 2, the recommendations distinguish been gelatin made from hides and skin (Subpart 1, d) and gelatin prepared from bones (Subpart 2 c). Gelatin made from hides and skin can be traded without restriction based on the BSE status of the country while gelatin from bone can be traded subject to prescribe conditions related to the BSE status of the cattle in the exporting country. The presumption is that bone gelatin carries a BSE risk no matter how the gelatin is used and that the risk is associated with gelatin-exporting country. However, this logic is of concern on two grounds. First, for a risk to human or animal health to be present, there must be exposure of humans or animals to gelatin. If there is no exposure, there is no risk, even if the BSE agent were present. The risks to human and animal heath associated with BSE are due to ingestion of contaminated feed for animals and ingestion of contaminated beef products for humans. However, gelatins manufactured for industrial uses do not present such a risk, as there is no significant exposure of humans or animals to the gelatins in these products. In the definition of industrial uses we would include medical devices with no significant human or animal contact such as X-ray film and in vitro medical devices.

Article 2.3.13.19 and Article 2.3.13.20:

Article 2.3.13.19.

1) From cattle of any age originating from a country or zone with a moderate or a high BSE risk, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices (except for X-Ray film, *in vitro* devices, and other industrial uses not intended for animal or human use): tonsils and intestine, and protein products derived from them. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

2) From cattle originating from a country or zone with a moderate or a high BSE risk, that were at the time of slaughter over ~~6~~ 12 months of age, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices (except for X-Ray film, *in vitro* devices, and other industrial uses not intended for animal or human use): : brains, eyes, spinal cord, ~~tonsils, thymus, spleen, intestines, dorsal root ganglia, trigeminal ganglia~~, skull and vertebral column and ~~derived~~ protein products derived from the preceding. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices (except for X-Ray film, *in vitro* devices, and other industrial uses not intended for animal or human use): prepared using these commodities should also not be traded.

~~From cattle, originating from a country or zone with a moderate BSE risk, that were at the time of slaughter over 6 months of age, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, distal ileum, skull, vertebral column and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.~~

3) From cattle, originating from a country or zone with a minimal BSE risk, that were at the time of slaughter over 30 months of age, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices (except for X-Ray film, *in vitro* devices, and other industrial uses not intended for animal or human use): brains, eyes and spinal cord, skull, vertebral column and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

Article 2.3.13.20.

Veterinary Administrations of *importing countries* should require:

for gelatin and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices (except for X-Ray film, *in vitro* devices, and other industrial uses not intended for animal or human use): the presentation of an *international veterinary certificate* attesting that the bones came from:

1) a BSE free or provisionally free country or zone, or from a country or zone with a minimal BSE risk; or

2) a country or zone with a moderate BSE risk; and

   a) skulls and vertebrae (excluding tail vertebrae) have been excluded;

   b) the bones have been subjected to a process which includes all the following steps:

      i) pressure washing (degreasing),

      ii) acid demineralisation,

      iii) prolonged alkaline treatment,

      iv) filtration,

      v) sterilisation at ≥138°C for a minimum of 4 seconds,

      or to an equivalent process in terms of infectivity reduction.

Rationale: These articles contain several references to medical devices without any qualification. Some medical devices are manufactured with bone gelatin, notably X-ray film and in vitro diagnostic tests. However, these medical devices present no human or animal health risk from BSE as there is no significant human or animal contact with these devices. Because there is no risk, we recommended that these medical devices should be exempted from restrictions and requirements of Article 2.3.13.19. and Article 2.3.13.20.